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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,066	10/06/2000	Rama Ranganathan	UTSD:645US/MTG	2858

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/684,066	<b>Applicant(s)</b> RANGANATHAN ET AL.	
	<b>Examiner</b> Lori A. Clow, Ph.D.	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

S.O.O.

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### **DETAILED ACTION**

Applicants' arguments, filed 22 April 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-18 and 35 are currently pending.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 35 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the previous Office Action.

#### **Response to Applicant's Arguments**

A. *"The claims are, in essence, concerned with mathematics"*

The Examiner disagrees with this position as the claims are clearly drawn to bioinformatics, which encompasses mathematical calculations and computer implemented parameters within the areas of the biological sciences. Applicant is reminded that the

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enablement rejection is not focused on the equation, rather it pertains to the use of **any** polymer in step (a). Applicant is reminded that identifying one or more evolutionarily conserved amino acid positions (in step (b)) in a chemical polymer is nonsense if the chemical polymer does not include a polypeptide/protein. The specification, at page 16, indicates that only protein sequences can be aligned, but is completely devoid of information as to how any other type of polymer is to be selected and aligned. Further, the claims do not set forth that the polymers to be aligned are from a single protein family or from related proteins. There is no requirement for a base level of similarity for the multiple sequence alignment such that one of ordinary skill in the art would be able to select appropriate sequences for use in this method.

*B. "Claim 1's recitation of 'identifying one or more evolutionarily conserved amino acid positions within the MSA' using the claimed equation, which specifies parameters that are defined in the claim, can necessarily be performed if the claimed parameters are known or determined (e.g., through calculation) and the MSA concerns a polymer that has one or more amino acid positions"*

The Examiner maintains that accessing data representing a multiple sequence alignment (MSA) of a plurality of polymer sequences and then identifying one or more evolutionarily conserved amino acid positions within the MSA is not enabled if the polymer is any other polymer than a protein/polypeptide, for which the specification is enabled. It is possible in the art that MSAs may be used to align polysaccharides, for instance. However, the claimed invention is not enabled for identifying one or more evolutionarily conserved amino acid

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positions from a polysaccharide. This makes no sense. The specification **only** enables identification of evolutionarily conserved amino acid positions within a protein/polypeptide.

C. *“To illustrate the predictability of this art and the applicability of the methods of claims 1 and 10 to MSAs of polymers other than those from the PDZ domain family, Dr. Raganathan [demonstrates] a method that could be used to fulfill the steps of claim 1 (if one or more evolutionarily conserved amino acid positions are identified) or claim 10 (if conservation energy value for each position in the MSA is calculated, and one or more positions with statistically significant conservation energy values are identified) to an arbitrary model MSA of a made-up polymer”.*

The Examiner maintains that the **specification** is not enabled for **any** polymer, rather only biological polymers, more particular, protein/polypeptide. The instant claims are not enabled for a finding evolutionarily conserved amino acids in plastic, for instance.

D. *“Chemical polymers exist that have one or more amino acids but do not include protein, thus the Office’s statement that “identifying one or more evolutionarily conserved amino acid positions in a chemical polymer is nonsense if the chemical polymer does not include protein”.*

The Examiner maintains that this is not nonsense if the polymer is one that does not include amino acids. The method is enabled for a protein or polypeptide, as is set forth above but is not enabled for any polymer which does NOT comprise amino acids. If the polymer were a polysaccharide, for example, as stated above, step (b) of claim 1 cannot be performed.

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E. *"Applicants are not obliged to identify all the different MSAs to which the claimed invention could be applied".*

This is not persuasive as the rejection at hand is one of enablement and not written description. As stated above, the claims are not enabled for **any** polymer.

F. *"The specification states that 'any polymer of monomers may be analyzed with the inventive methods. Application of the inventive methods is not limited to biological sequences, as it may be applied to chemical polymers, drugs, and other compounds'".*

This is not persuasive, as the specification fails to teach how the method is applicable to any known polymer, as stated above.

G. *"As Applicant has stated before, the claims relate to accessing data representing an MSA; they do not recite the creation of an MSA".*

As the Examiner has stated before, it is acknowledged that the claims are not directed to creation of an MSA. This does not enable the claims for any known polymer. Biological sequences may be aligned, but there is nothing in the specification that teaches how to align polystyrene, for example. And certainly, identification of evolutionarily conserved amino acid positions in polystyrene is not enabled, as it does not even contain amino acids. If the polymer of step (a) is anything other than a protein/polypeptide, the claims are not enabled.

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**Declaration**

The declaration submitted 22 April 2005 is not persuasive to overcome the enablement rejection of record, for the reasons set forth above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

June 29, 2005

Lori A. Clow, Ph.D.

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*Lori A. Clow*

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
*6/30/05*